UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 Civil Action No. 01-12257-PBS
	Judge Patti B. Saris
THIS DOCUMENT RELATES TO: *The City of New York v. Abbott Labs., et al.* (S.D.N.Y. No. 04-CV-06054) *County of Suffolk v. Abbott Labs., et al.* (E.D.N.Y. No. CV-03-229) *County of Westchester v. Abbott Labs., et al.* (S.D.N.Y. No. 03-CV-6178) *County of Rockland v. Abbott Labs., et al.* (S.D.N.Y. No. 03-CV-7055) *County of Dutchess v. Abbott Labs., et al.* (S.D.N.Y. No. 05-CV-06458) *County of Putnam v. Abbott Labs., et al.* (S.D.N.Y. No. 05-CV-04740) *County of Washington v. Abbott Labs., et al.* (N.D.N.Y. No. 05-CV-00408) *County of Rensselaer v. Abbott Labs., et al.* (N.D.N.Y. No. 05-CV-00422) *County of Albany v. Abbott Labs., et al* (N.D.N.Y. No. 05-CV-00425)	

[Caption Continues on Next Page]

DEFENDANT SANDOZ INC'S SUPPLEMENTAL MEMORANDUM OF LAW REGARDING MULTIPLE SOURCE GENERIC DRUG PRODUCTS IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE CORRECTED CONSOLIDATED COMPLAINT AND THE SECOND AMENDED COMPLAINT OF NASSAU COUNTY

County of Warren v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00468))
County of Greene v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00474))
County of Saratoga v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00478))
County of Columbia v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00867))
Essex County v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00878))
County of Chenango v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00354))
County of Broome v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00456))
County of Onondaga v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00088))
County of Tompkins v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00397))
County of Cayuga v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00423))
County of Madison v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00714))
County of Cortland v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00881))
County of Herkimer v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00415))
County of Oneida v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00489))
County of Fulton v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00519))
County of St. Lawrence v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00479))
County of Jefferson v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00715))
County of Lewis v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00839))
County of Chautauqua v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-06204))
County of Allegany v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-06231))
County of Cattaraugus v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-06242))

County of Genesee v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-06206))
County of Wayne v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-06138))
County of Monroe v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-06148))
County of Yates v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-06172))
County of Niagara v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-06296))
County of Seneca v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-06370))
County of Orleans v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-06371))
County of Ontario v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-06373))
County of Schuyler v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-06387))
County of Steuben v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-06223))
County of Chemung v. Abbott Labs., et al.)
(W.D.N.Y. No. 05-CV-06744))
AND)
County of Nassau v. Abbott Labs., et al.)
(E.D.N.Y. No. 04-CV-5126))
_____)

Defendant Sandoz Inc., joined by certain other Defendants, respectfully submits this supplemental memorandum of law to further demonstrate that the Consolidated Complaint (the "Consolidated Complaint") and the Second Amended Complaint of Nassau County (the "Nassau Complaint") must be dismissed to the extent that Plaintiffs' claims relate to Medicaid reimbursements for drugs categorized as "multiple source generic drugs," and commonly referred to as "generic drugs."[1]

Plaintiffs' theory is that every Defendant, including Sandoz, reported "false and inflated" Average Wholesale Prices ("AWPs") and wholesale acquisition costs ("WACs") for their products to create favorable "spreads" between the actual prices at which pharmacies (and other providers) purchased their drugs and the reimbursements they would receive from the New York Medicaid program. Consolidated Complt. ¶¶ 8-12, 16; Nassau Complt. ¶¶ 2-4; 7-11. Plaintiffs concede, however, that New York Medicaid reimbursed pharmacies for many generic drugs identified in the Complaints pursuant to formulas that do not refer to AWP (or WAC).[2] See generally Consolidated Complt. ¶87; Nassau Complt. ¶84 (alleging that New York Medicaid paid reimbursements for generic drugs at the Federal Upper Limit).

Setting aside the other flaws with Plaintiffs' theory, this concession is fatal to Plaintiffs' claims because they must still show that the New York Medicaid program relied on, and was injured by, an allegedly fraudulent AWP. See, e.g., Weissman v. Mertz et al., 128 A.D.2d 609, 610, 512 N.Y.S.2d 865, 867 (2d Dep't 1987) (dismissing fraud claim where "nothing in the record

[1] Each of the following Defendants joins this memorandum as to those cases in which it is a party: Abbott Laboratories, Inc., Alpharma, Inc., Barr Laboratories, Inc., Ben Venue Laboratories, Inc., Roxane Laboratories, Inc., Dey, Inc., Dey, L.P., ETHEX Corporation, Ivax Corporation, Ivax Pharmaceuticals, Inc., Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc., Mylan Laboratories Inc., Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc., Pharmacia Corporation, Greenstone Ltd., Purepac Pharmaceuticals Co., Sicor Inc., Teva Pharmecuticals USA, Warrick Pharmaceuticals Corp., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Wyeth. Each of these Defendants also joins in the Defendants' Joint Memorandum of Law in Support of Defendants' Motion to Dismiss the Consolidated Complaint and the Nassau Complaint.

[2] Both federal and New York law distinguish between "brand name" drugs and their "generic" (or "multiple source generic drugs") counterparts for purposes of determining Medicaid reimbursements. See New York Soc. Serv. § 376-a(9)(b)(ii) (distinguishing reimbursement calculations for "sole and multiple source brand name drugs" and "multiple source generic drugs.")

[indicates] that the appellants' misrepresentations were the proximate cause of the plaintiff's damages, which are speculative at best."); Colavito v. New York Donor Network, Inc., 356 F. Supp. 2d 237, 241 (E.D.N.Y. 2005) ("to succeed on a claim for fraud there must be some action the plaintiff took because of the defendants' alleged misrepresentations that caused him harm") (applying New York law).

Thus, in addition to other pleading failures, the Complaints must be dismissed pursuant to Rule 9(b) because Plaintiffs do not identify the formula that applied to the reimbursements of Sandoz' products allegedly giving rise to Plaintiffs' claims, and have not alleged that any individual AWP reported by Sandoz caused New York Medicaid to overpay reimbursements. Indeed, to the extent that Sandoz products were reimbursed pursuant to the non-AWP formulas, Plaintiffs' claims should be dismissed pursuant to Rule 12(b) because they will be unable to show that New York Medicaid overpaid as a result of Sandoz' (or other Defendants') reported AWPs.

BACKGROUND

During the period covered by the Complaints, New York Medicaid has paid reimbursement for generic drugs under several different formulas, only some of which involve an AWP published in the commercial compendia, such as First Data Bank and the Red Book. For most of this period, New York Medicaid paid the lowest of (a) the estimated acquisition cost, a New York State-determined formula set at AWP minus a specified percentage; (b) the "dispensing pharmacy's usual and customary price charged to the general public"; or (c) the Federal Upper Limit ("FUL"), which is set by the federal Centers for Medicare and Medicaid ("CMS"). N.Y. Soc. Serv. L. § 367-a.[3]

CMS will set a FUL whenever the compendia indicate that there are three suppliers of the same therapeutically equivalent drug. A FUL equals 150% of the lowest price published in the

[3] From July 1, 1990 to March 31, 1994, New York law did not include any specific reimbursement scheme; it simply required that the department establish payment levels for multisource prescription drugs consistent with federal law and regulations. N.Y. Soc. Serv. L. § 367-a(9).

compendia for that particular drug, which could be the drug's AWP, WAC or direct price. See 42 C.F.R. §§ 447.331, 332 (2004); 52 Fed. Reg. 28, 648 (July 31, 1987). Thus, because, as Plaintiffs allege, a drug's reported WAC generally is lower than its reported AWP, Consolidated Complt. ¶7; Nassau Complt. ¶5, the FUL could be equal to 150% of the lowest WAC reported by any company, not of an AWP.[4]

ARGUMENT

PLAINTIFFS HAVE NOT PLED RELIANCE OR A CAUSAL CONNECTION BETWEEN THE ALLEGED FRAUD AND THEIR CLAIMED INJURIES

Insofar as Plaintiffs' claims sound in fraud, they must allege a causal connection between the alleged fraud (reporting AWPs and WACs) and the alleged injury (paying too much in Medicaid reimbursement). See Water Street Leasehold LLC v. Deloitte & Touche LLP, 19 A.D.3d 183, 185, 796 N.Y.S.2d 598, 599-600 (1st Dep't 2005) (loss causation is an essential element of any fraud claim); Colavito, 356 F. Supp. 2d 237, 241 ("to succeed on a claim for fraud there must be some action the plaintiff took because of the defendants' alleged misrepresentations that caused him harm.") As shown below, however, despite hundred of pages of written allegations and multiple exhibits, Plaintiffs have not made allegations particularizing the alleged fraud: they have not alleged which, if any, of Sandoz' products (or any other multiple source generic products) New York Medicaid paid reimbursement on the basis of a reported AWP (or WAC). In addition to these pleading deficiencies, Plaintiffs' theory fails to the extent that they purport to state claims for those reimbursements that were not based on an AWP.

As summarized above, over the period covered by the Complaints, New York Medicaid has used different reimbursement formulas for generic drugs, including three – the usual or

[4] Recently, in April 2004, New York amended its reimbursement for non-FUL drugs to add a third alternative formula for reimbursement of multiple source generic drugs: the "maximum acquisition cost," which is an interim price to be used for multiple source generic drugs "when no specific upper limit" has been set by CMS. The maximum acquisition cost is calculated by the Commissioner of Health using a "similar methodology" as that utilized by CMS in establishing the FUL. N.Y. Soc. Services L. § 367-a(9)(e).

customary price, FUL, and the recently added maximum acquisition cost – that do not refer to an AWP reported in the compendia. Without product-specific and time-specific allegations that each of the reimbursements for Sandoz products that New York Medicaid paid was based on an AWP formula, Plaintiffs' claims must be dismissed for lack of specificity because Plaintiffs have not alleged a causal connection between Sandoz' AWPs and their alleged injury. See In re Pharmaceutical Industry Average Wholesale Price Litigation, 230 F.R.D. 61, 91 (D. Mass. 2005) (concluding that class-wide injury for generic reimbursements may only be shown to the extent that reimbursement "is expressly predicated on AWP.").

Plaintiffs cannot claim that their exhibits listing Sandoz' (and other Defendants') AWPs, alleged market prices, and the resulting "spreads" provide the required particularity. See Consolidated Complt. at Ex. B; Nassau Complt. at Ex. B. Even a cursory review demonstrates that Plaintiffs have not actually alleged that they relied on or were injured by the cited AWPs for the simple reason that many of the products were reimbursed at the FUL, not an AWP-based formula. See Consolidated Complt. ¶87, Ex. C; Nassau Complt. ¶84, Ex. C.

To illustrate, Exhibit B to the Consolidated Complaint states that that the pricing of Sandoz' Albuterol Sulfate 2 mg tablet (100-units), as of December 12, 2000, created a 983.01% spread between the AWP of $28.05 and the alleged market price of $2.59. However, since at least November 2000, a FUL of $.0380 (or $3.80 per 100-units) has been in place for this drug. See Consolidated Complt. Ex. B at 75, Ex. C; see also http://www.cms.hhs.gov/Federal .UpperLimits/Downloads/TransmittalNo36April2000.pdf. Hence, neither the AWP nor the alleged spread listed for Sandoz' Albuterol Sulfate 2 mg tablet had any effect on New York Medicaid paying reimbursement at the FUL. Other such examples include Sandoz' Furosemide tablets, Meclizine 25 mg tablets, and Verapamil 120 mg; for which Plaintiffs include data for December

2000 even though a FUL was in place for each of these drugs at the time. Id.[5]

Plaintiffs may also contend that Sandoz' (and other Defendants') allegedly inflated AWPs (and WACs) caused injury by affecting the rate at which the federal government set the FUL. See Consolidated Complt. ¶¶ 86-87; Nassau Complt. ¶83 (where New York Medicaid reimbursed at the FUL, it "overpa[id] as a result of Defendants' fraud."). But this contention also would fail because Plaintiffs simply make no allegations as to which, if any, of Sandoz' (or other Defendants') reported prices that Plaintiffs allege to be fraudulent were actually used by CMS to set a FUL.

In sum, as this analysis demonstrates, Plaintiffs have utterly failed to meet the Court's directive to provide enough detail to support their claims. See Massachusetts v. Mylan Laboratories, No. 03-11865-PBS, 2 (April 5, 2005) (mem.) ("Thus, the Complaint is not sufficient to meet the requirements that Massachusetts plead the 'time, place, and content of the alleged false or fraudulent representations.' The Complaint may be amended to state, drug-by-drug, the allegedly false representation.") (internal citation omitted).

CONCLUSION

For the foregoing reasons, as well as those set forth in the Joint Memorandum, undersigned Defendants respectfully request that this Court dismiss the Complaints.

Dated: March 3, 2006
New York, New York

Respectfully submitted,

By: /s/ Michael J. Gallagher

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[5] The Nassau Complaint has the same flaws. For example, it cites AWPs, as of 2003, for Desipramine 50 mg tablets, Diclofenac Potassium 50 mg tablets, and Perphenazine 8 mg even though a FUL has been in place for each of these drugs since November 2000. (Nassau Complt. Ex. B at 58-63; see also http://www.cms.hhs.gov/FederalUpperLimits/Downloads/TransmittalNo36April2000.pdf).

CERTIFICATE OF SERVICE

I hereby certify that on March 3, 2006, I caused a true and correct copy of the Defendant SANDOZ INC's SUPPLEMENTAL MEMORANDUM OF LAW REGARDING MULTIPLE SOURCE GENERIC DRUG PRODUCTS IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE CORRECTED CONSOLIDATED COMPLAINT AND THE SECOND AMENDED COMPLAINT OF NASSAU COUNTY to be served on all counsel of record by electronic service, accordance with Case Management Order No.2, by sending a copy to Verilaw Technologies for posting and notification to all parties.

/s/ Sheryl L. Dickey

Sheryl L. Dickey